K002256

SECTION 2 – 510(k) SUMMARY

510(k) SUMMARY

MAY - 3 2001

This device is substantially equivalent to the following legally marketed intra-aortic balloon pumps:

1. Belmont Model NGPBP IABP from Belmont Instruments Corporation, Billerica, MA;
2. The ACAT 1, from Arrow International, Everett, MA;
3. The KAAT II Plus IABP, from Arrow International, Everett, MA;
4. The System 95 and 97 IABP, from Datascope Corporation, Paramus, NJ;
5. The BARD Transact System H8000, from Belmont Instruments Corporation, Billerica, MA.

The ACAT 2 IABP is the next generation of the Arrow ACAT 1 IABP manufactured by Arrow International.

The purpose of the new ACAT 2 is to convert the original ACAT 1, which is a manual adjustment system, into an one button automatic or manual IABP system. This will be accomplished through the development of new software algorithms. The existing ACAT 1 hardware, electronics, pump assembly and packaging designs are the same for the ACAT 2 IABP.

NOTE: This is a software update to the existing ACAT 1 IABP only.

This software has been developed to meet customer requirements and/or preferences. The software is identical to the ACAT 1 software, with the addition of an "Optimized" mode. The Optimized mode employs greater device involvement in detecting the patient's heartbeat and timing the inflation and deflation of the Intra-Aortic Balloon (IAB), thus reducing the requirements for intense monitoring by a qualified Cardiologist or Perfusionist.

The device is indicated for the following conditions:
Cardiogenic shock, Pre-shock syndrome, Post-infarction angina (Threatening extension of MI) Unstable refractory angina, or impending infraction, Ischemia related intractable ventricular dysrhythmias, Septic shock syndrome, Cardiac contusion, Support for diagnostic interventional procedures including: (Cardiac Angiography, Coronary Angioplasty (PTCA), Failed Thrombolytic Therapy, Coronary Atherectomy, Failed Mitral Valvuloplasty), Mechanical complications due to acute myocardial infraction: (Valvular stenosis – Mitral stenosis, Mitral Valve insufficiency – Mitral regurgitation, Ventricular Septal Defect (VSD), Papillary muscle rupture), Prophylactic support in preparation for cardiac surgery or high risk cardiac patients undergoing non-cardiac surgical procedures, Post-surgical myocardial dysfunction, Cardiac support following correction of anatomical defects, Maintenance of graft patency post-coronary bypass surgery, Pulsatile flow during cardiopulmonary bypass, Mechanical bridge to other assist devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

ARROW INTERNATIONAL, INC.
c/o Mr. William Paquin
Quality Assurance/Regulatory Affairs Manager
9 Plymouth Street
Everett, MA 02149

Re: K002256
Trade Name: ARROW ACAT 2 INTRA-AORTIC BALLOON PUMP
Regulatory Class: III (three)
Product Code: DSP
Dated: January 30, 2001
Received: February 2, 2001

Dear Mr. Paquin:

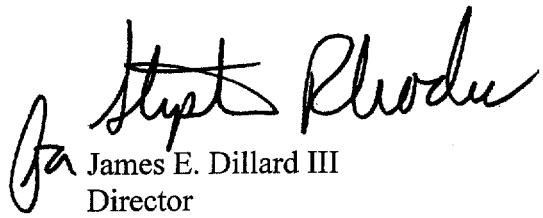
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number
(800) 638-2041 or (301) 443-6597 or at its internet address
"http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K002256

MAY - 4 2001

ARROW
International

9 Plymouth Street
Everett, MA 02149

(617) 389-6400
FAX: (617) 387-2157

SECTION 11 - INDICATIONS

Indications for IABP use are as follows:

- Cardiogenic shock
- Pre-shock syndrome
- Post- Infarction angina (Threatening extension of MI)
- Unstable refractory angina, or impending infraction
- Ischemia related intractable ventricular dysrhythmias
- Septic shock syndrome
- Cardiac contusion
- Support for diagnostic interventional procedures including:
  - Cardiac Angiography
  - Coronary Angioplasty (PTCA)
  - Failed Thrombolytic Therapy
  - Coronary Atherectomy
  - Failed Mitral Valvuloplasty
- Mechanical complications due to acute myocardial infraction:
  - Valvular stenosis – Mitral stenosis
  - Mitral Valve insufficiency – Mitral regurgitation
  - Ventricular Septal Defect (VSD)
  - Papillary muscle rupture
- Prophylactic support in preparation for cardiac surgery or high risk cardiac patients undergoing non cardiac surgical procedures
- Post-surgical myocardial dysfunction
- Cardiac support following correction of anatomical defects
- Maintenance of graft patency post coronary bypass surgery
- Pulsatile flow during cardiopulmonary bypass
- Mechanical bridge to other assist devices.

Division of Cardiovascular & Respiratory Devices
510(k) Number K002256

✓ Prescription Use